# Legal considerations of clinical guidelines: will NICE make a difference?

Ash Samanta MD LLB Jo Samanta BA[1] Michael Gunn LLB[2]

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Clinical guidelines are statements that have been systematically developed and which aim to assist clinicians in making decisions about treatment for specific conditions[1]. They are linked to evidence and are meant to facilitate good medical practice. The National Institute for Clinical Excellence (NICE) is part of the Government's agenda for healthcare. One of its main functions is to develop, issue and encourage the use of objective guidelines, thus promoting 'best practice'. A key issue that follows is how lawyers and the courts might use such guidelines in medical litigation.

At the heart of clinical negligence lies the question of whether or not the practice of a defendant doctor has fallen below the required standard of care. Under common law in the UK, the minimal acceptable standard of care is measured against responsible medical practice, and not against guidelines[2]. In law, therefore, it is expert medical evidence that primarily assists the court in determining what the standard of care should be, and until now clinical guidelines have played a subsidiary role.

This paper discusses the role of guidelines within the context of the tort of negligence, with reference to their use currently and the possible medicolegal implications of guidelines from NICE in the future.

## DEVELOPMENT, BENEFITS, LIMITATIONS AND USE OF GUIDELINES

The development of guidelines is a structured process[3]. The first step is to identify and refine the subject area. A multidisciplinary expert group of key stakeholders systematically reviews all the available evidence. The group proceeds to identify and assess relevant evidence around the subject, which then needs to be translated into a practically useable and workable clinical form. Guidelines need to be reviewed and updated regularly[4].

Clinical guidelines are developed by the techniques of evidence-based medicine. Their potential benefits include provision of a robust management strategy for patients, and maintenance of consistency and quality in healthcare[5]. However, guidelines need to be interpreted and applied in a way that is clinically appropriate, and they represent just one option for improving the overall quality of clinical care[6].

Guidelines are not without their limitations. The primary data, which form the evidence for developing guidelines, are of necessity derived from a sample population. Susceptibility to bias relating to the nature of evidence, misconceptions, and personal recollections dependent upon the beliefs of the developers are some of the factors that may confound the validity of guidelines[7]. A further difficulty arises from the generalization that such evidence is equally applicable to every individual[3]. Clinical judgment may suggest otherwise; guidelines are not 'magic bullets', and enthusiasm for them must be tempered with caution[5].

The past few years have seen a proliferation of clinical guidelines from various authoritative bodies. Since these are evidence-based and intended to facilitate best practice, one might expect them to be widely used; however, the existence of a good guideline does not guarantee either wide or consistent use[8]. Diverse factors that influence the behaviour of health professionals[9] might account for the disparate use of guidelines[10]. The uptake in clinical practice is disappointingly low[11]. In the Netherlands a study commissioned by the Health Council indicated that guidelines had been followed in only 55% of clinical decisions[12]. Perhaps the reason lies in the inability of guidelines to address all the uncertainties inherent in clinical practice.

## THE USE OF CLINICAL GUIDELINES IN LAW: AN ANGLO-AMERICAN PERSPECTIVE

### USA

A large number of clinical guidelines exist in the USA, and their role in medical malpractice litigation has been extensively analysed[13].

From the perspective of litigation, the key question has been whether guidelines can be admitted as evidence of the standard of expected practice, or whether this would be regarded as hearsay. Courts in the USA have been unwilling to adopt broad exceptions to the hearsay rule, which limits

Musculo-skeletal Directorate, University Hospitals of Leicester NHS Trust, Leicester Royal Infirmary, Leicester LE1 5WW, UK; [1]Academic Department of Law, De Montfort University, Leicester; [2]Department of Academic Legal Studies, Nottingham Law School, Nottingham Trent University, Nottingham, UK

Correspondence to: Dr Ash Samanta
E-mail: ash.samanta@uhl-tr.nhs.uk

the admissibility of out-of-court statements where the author of the statement has not been sworn as a witness and is therefore not available for cross examination. Guidelines may be admissible as evidence in the USA if qualified as authoritative material or a learned treatise, although a US Supreme Court decision[14] may encourage US judges objectively to scrutinize the motivation and rationale behind guidelines before accepting their evidential value. In the UK, there is currently no effective hearsay rule in civil proceedings.

Little has been published on the actual use of guidelines in litigation. In the Hyams study[15], the authors reviewed 259 claims of two professional liability insurance companies. Only 17 (7%) of the claims involved the use of clinical guidelines. Of these 17, 12 were used by the claimant (as a sword), 4 by the defendant (as a shield) and in 1 the use was indeterminate. The study also surveyed the views of lawyers regarding the use of guidelines. 980 lawyers from all fifty States of the USA were surveyed and 399 responded. 48% had at least one case per year in which guidelines played some part, but only 36% had one case per year in which clinical guidelines played an important part. Interestingly, only 22% stated that a clinical guideline had influenced a judge or jury in at least one case in the previous year. These findings indicate that, in the area of medical malpractice, guidelines are seldom an issue and that their impact on the outcomes is modest. There are no equivalent data from the UK.

Non-adherence to established guidelines does not necessarily bode an adverse outcome for the defendant. In *Lowry*[16] the claimants argued that the treating physician had arbitrarily deviated from the American Heart Association's guidelines for advanced cardiac life support by administering atropine rather than epinephrine. The defendant physician argued that guidelines were not mandatory and therefore could be overridden by clinical judgment in an individual case. The Appeal Court affirmed the judgment in favour of the defendant and did not see guidelines as being more persuasive than the facts of the case itself.

Adherence to guidelines may not exonerate the defendant. Although clinical guidelines may be acknowledged as relevant, the courts in the USA will take into account other sources of information in determining the standard of care, which would include factors such as the hospital's own procedures and policies, and expert evidence[17]. The claimant in *Helling*[18], appealing from a judgment in favour of an ophthalmologist, argued that the customary standard of care presented was inadequate and therefore unreasonable. In finding for the claimant, the Washington Supreme Court refused to be bound by widely endorsed clinical guidelines that formed the basis of the standard proclaimed by the defendant. Thus there is no absolute judicial deference to compliance with clinical guidelines.

The position of an affirmative defence, based on practice conforming to guidelines that have been defined into legislation, is unclear. In 1990, the Maine legislature was the first in the USA to legislate that guidelines could be used as a defence in clinical negligence[19]. The project was primarily aimed to reduce the practice of defensive medicine and thus lower costs by reducing the payment for unnecessary tests and procedures. A physician's compliance with established guidelines would rebut the charge that the physician had not met the standard of care. The success of this project has been difficult to evaluate since there are no reliable data to show whether defensive practice had actually decreased, or whether any reduction was achieved in the number of defensive-medicine procedures performed. In 1992 Florida State legislature established a project to evaluate the effectiveness of practice guidelines with regard to the costs of defensive medicine and professional liability. This project concluded that there was no known use of guidelines in courts as an affirmative defence[20].

Despite the profusion of clinical guidelines in the USA, their actual use in medical litigation has been low. Guidelines may have some relevance towards determining the standard of care required in law; however, conformity to guidelines would not automatically qualify as an affirmative defence in a medical malpractice claim.

## UK

In the UK the legal standard of care has been enshrined in the *Bolam* test[21]. This test is based on the principle that the standard of care provided by a medical practitioner, in law, depends upon what is done in practice. A doctor can rebut a charge of negligence if he or she has acted in conformity with a similar body of other responsible and skilled professionals. Guidelines, therefore, do not have a 'self-evident' status; they have a subservient role to that of evidence provided by the expert witness[2]. *Loveday*[22] clearly exemplifies a judicial favour towards this approach. Stuart Smith LJ, speaking about published contraindications to the pertussis vaccine, preferred the evidence of expert witnesses above written material published by learned bodies. The judge said 'The evidence contained in the contraindications against pertussis vaccination published from time to time in this country by the DHSS and similar bodies in other countries *cannot be relied upon as though it was evidence of qualified experts not called in witness*' (emphasis added).

A shift towards the use of guidelines in determining the standard of care was seen in the case of *Early*[23], a judgment at first instance. The defendants were sued on two grounds.

The first was that the attending anaesthetist was negligent, and the second was that the procedure adopted to intubate the claimant was faulty. The procedure used for intubation had been based on an orally stated guideline. Both claims failed, and the judge said: 'In relation to this procedure, it was put before the division of anaesthesia in the hospital. All the consultants at Newham got together . . . who then decided that this was a proper procedure to follow and minutes of the discussion were kept'. The judge clearly showed that he was influenced by the fact that a meeting of the consultants had taken place where relevant guidelines were discussed, and he accepted these guidelines as the standard of reasonable medical practice.

In recent years the higher courts have articulated that guidelines may be relevant in determining the standard of care. In *Re C*[24] the High Court said of guidance issued by the Royal College of Paediatrics and Child Health that it was 'clear that what ha[d] been proposed by the doctors ha[d] the support of [the College], who considered the wide field of these matters in their meetings, which led to the publication of the document'. The Court of Appeal approved of the decision at first instance in *Penney*[25] at which the judge found for the claimants and was persuaded by the force of national guidelines in determining the standard of care. The House of Lords in *Bland*[26] considered guidelines produced by the medical ethics committee of the BMA regarding discontinuation of artificial nutrition and hydration. Lord Goff said: 'If a doctor . . . acts in accordance with the medical practice now being evolved by the Medical Ethics Committee of the BMA, he will be acting with the benefit of guidance from a responsible and competent body of relevant professional opinion'. These recent cases illustrate that courts at all levels are willing to accept that national and authoritative guidelines reflect not only responsible but also reasonable medical practice. This could be instrumental in setting the legal standard of care.

There is, nonetheless, a fear that departure from guidelines could be seen as giving rise to a case to answer[27] and that rigid adherence to guidelines could erode and diminish clinical judgment[28]. Clinical judgments often go to issues beyond scientific evidence and incorporate considerations of attitudes and values, expectations and patient choice[29]. The application of guidelines in practice must link these issues to scientific evidence[30]. There is an argument therefore that there should be no legal expectation for doctors to follow guidelines.

Recent analysis suggests that clinical guidelines may have a more complex part to play in the law of clinical negligence in the UK[31,32]. This is because the use of guidelines in clinical practice cannot be viewed as divorced from their possible use in setting the expected standard of care in law. It is our opinion that the traditional subsidiary role of clinical guidelines in medical litigation may be altered in the case of guidelines from NICE.

## GOVERNMENT AGENDA FOR HEALTHCARE AND NICE

The World Health Organization has declared that governments must take responsibility for their healthcare systems[33] and proposes a concept of 'stewardship' that implies active involvement in the nature and quality of services provided[34]. The UK Government has announced plans to modernize the National Health Service. The Health Act 1999 was passed to ensure uniformly high quality care for all patients. The Act came into force in July 1999 and section 18 imposes a statutory duty of quality on all health authorities, NHS trusts and primary care trusts alongside the duty of care already owed to patients at common law.

NICE was established on 1 April 1999 as a Special Health Authority created by means of a statutory instrument[35] under the provisions of section 11 of the National Health Service Act 1977. NICE has its own legal identity with direct responsibility to the Secretary of State. One of its main functions is to develop guidelines on best practice and clinical management. In assessing the status that such guidelines may have, two principal factors need to be considered—namely, the quality of the material and the quality of the process used in their formulation.

Evidence-based guidelines are developed by NICE from the highest level of evidence. Well-structured high-quality trials will be the material from which the most reliable inferences can be drawn[36]. Guidelines from NICE would therefore be regarded as carrying considerable scientific weight.

The process by which such guidelines are formulated is based upon the principle of 'reasonableness and accountability' expected of a public body. This means that decisions must be publicly accessible, that the rationale must rest on evidence, that there is a mechanism for appealing against decisions, and that there is regulation of the process[37]. These conditions are fulfilled by NICE in its decision-making process[38]. This does not mean that decisions by NICE are immune to challenge, and there have indeed been challenges by judicial review[38]. However, the procedural focus taken by NICE in reaching its decision, together with the continuing articulation of standards of good administration, helps to promote transparency and build trust and confidence in the legitimacy of its process[38].

Why should NICE guidelines have a greater status in law than guidelines produced in the past? Pre-NICE guidelines, it can be argued, were often developed by a similarly rigorous process, and at least some guidelines may have been produced for NICE by external developers using standard techniques. Nevertheless it is our contention that

guidance from NICE will be accorded greater weight in court. This is not just because these guidelines are strongly supported by government policy. They are also concurrent with the demand for clinical governance in the present climate of medical practice, and they come at a time when the future of medical litigation is undergoing a change. It is this combination of events that could accord guidelines from NICE a different status in law, compared with guidelines in the past, and this is discussed further.

## GOVERNMENT POLICY FOR HEALTHCARE QUALITY

The current UK Government is committed to adopting an approach that will ensure uniformity and consistency of healthcare throughout the country. This is endorsed by the expectation that NICE will give a strong lead on 'drawing up new guidelines and ensuring that they reach all parts of the Health Service'[1] and 'we will expect the guidance produced by NICE to be implemented consistently across the NHS'[39]. Section 19 of the Health Act 1999 established the Commission for Health Improvement (CHI), which has overarching responsibility for the entire quality system in the NHS. CHI ensures that systems for upgrading the quality of healthcare are working satisfactorily, and has the remit to inspect and monitor local clinical governance arrangements.

The commitment of the Government to ensuring quality and accountability throughout the system by which the medical profession is regulated is further developed by the NHS Reform and Health Care Professions Act 2002. This Act has expanded the remit of the Commission to include audit and has given it more power. In April 2002, the Government announced its plan for the new Commission for Healthcare Audit and Inspection (CHAI) to subsume CHI, and to have additional responsibility for auditing and inspecting healthcare providers. The emphasis on inspection implies a harder edged and wider regulatory function for CHAI[40]. It is likely that in publishing information on performance, CHAI will take into account whether guidelines from NICE are followed, and adherence to such guidelines may come to be regarded as evidence of good practice. The Act also establishes a Council for the Regulation of Healthcare Professionals. The Council will have statutory powers enabling intervention in cases where it finds that the public interest is not being served. Guidelines from NICE could provide strong ammunition for determining the expected standard of medical care, should the Council need to intervene.

## THE PRESENT CLIMATE OF MEDICAL PRACTICE

Several 'scandals' have undermined public confidence in the medical profession, especially since the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary (the Kennedy report)[41]. A central part of the Government's response is that clinical governance arrangements must be implemented throughout the NHS. Clinical governance is defined as a framework through which NHS organizations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish[42]. It includes the establishing of clear lines of accountability, the setting of a risk management policy and the implementation of comprehensive programmes to improve quality systems, including clinical audit and the use of evidence-based medicine and guidelines in clinical practice. The General Medical Council[43] (GMC) and Royal Colleges[44] have recognized the importance of clinical governance in identifying and minimizing underperformance in medical practice. Their guidance on good medical care states that practice should be measured against established and respected guidelines. Evidence of practice that conforms to guidelines may need to be presented by individual clinicians in their applications for revalidation and reaccreditation.

The old culture of 'professional arrogance' and lack of respect for patients' values is no longer socially acceptable[45]. Patient empowerment is a strong theme in the new NHS. Several patient-centred organizations have emerged which voice the views and rights of patients as consumers of the health service. The National Patient Safety Agency (NPSA) is an independent organization networking with local reporting systems to receive information about adverse events and learn from such experiences. The Patient Advocacy and Liaison Services (PALS) provides patients with information about their treatment. Demands from agencies such as these may lead to a greater reliance on the use of authoritative guidelines.

## THE FUTURE OF MEDICAL LITIGATION

In the UK the standard of care in law in cases of clinical negligence is judged by the *Bolam* test[21]. However, the judgment in the case of *Bolitho*[46] adds a subtle gloss to the *Bolam* test. In *Bolitho* the court declared that it was not bound to find for a defendant simply because he leads evidence from a body of experts who genuinely believe that the defendant's practice conformed to sound medical practice. The court will require further evidence that the practice proclaimed has a logical basis, and that the defendant practitioner has weighed up the benefits and risks. In other words, after *Bolitho* the defendant would have to justify his stance in addition to having this endorsed by similar responsible practitioners. Evidence-based medicine and clinical guidelines will begin to have a sharper focus in specifying the required standard of care.

Some have argued that the current tort-based adversarial system of clinical negligence liability encourages the covering up of mistakes and wastes resources[45]. Options for reform include the use of alternative dispute resolution (ADR) and mediation. The use of alternative methods to resolve disputes is a key element of the overriding objective of the Civil Procedure Rules (CPR) 1998[47]. An unreasonable refusal to resort to ADR could be a relevant factor in deciding such issues as to the allocation of costs for parties to an action. In furtherance of the CPR, trusts may adopt individual strategies to settle out of court in the event of medical misadventures. As part of strategies in ADR, trusts may become more active in enforcing the use of clinical guidelines through their clinical governance structures.

## CONCLUSION

Clinical guidelines are systematically developed, evidence-based, clinically workable statements that aim to provide consistent and high quality care for patients. Thus far, their use in setting the standard of care in cases of medical litigation has been limited. This is because the traditional test in law for the standard of care is the *Bolam* test, which measures the standard of care against what is done, rather than what ought to be done, in medical practice. This is derived from expert witness testimony in court, and clinical guidelines have so far played a subsidiary role. In the future, clinical guidelines are likely to become more relevant to the law of clinical negligence. Fundamental to clinical negligence is whether or not a defendant doctor has breached the standard of care. The *Bolam* test has been perceived as a licence for the medical profession to set its own standard[48]. Recent clinical governance initiatives are crucial in setting the standard of practice for doctors in both primary and secondary care. Clinical guidelines form a vital part of clinical governance. Continual professional development and appraisal form part of the clinical governance strategy and are recognized as key elements for the process of revalidation by the medical profession's regulatory body, the GMC. A further impetus to compliance with externally endorsed standards may come through the process of patient empowerment. The public and patients are inevitably going to have a greater involvement in clinical decision-making through organizations such as NPSA and PALS. The demands of such groups would be for the use of nationally endorsed clinical standards.

The law of clinical negligence also shows signs of change. Traditionally, a claimant's case fails if a doctor's actions are *Bolam*-defensible. However, now this may additionally have to be *Bolitho*-justifiable. In other words, there may be a requirement for the defendant doctor to explain why a specific action was taken, or not, and to justify the action or inaction. If clinical guidelines are meant to enhance the quality of clinical care, then the courts might enquire why such guidelines were not followed and whether a decision not to follow them was reasonable.

Guidelines from NICE may take on a more indicative role, against which the standard of care in law is measured. They carry scientific weight and have the backing of CHAI, which has responsibility for inspecting, auditing and monitoring the quality of healthcare. At a time when there is a shift of judicial thinking in the determination of the expected standard of care, these guidelines could acquire more powerful status in court. Case law has long recognized the importance of doctors' keeping up to date[49] and being able to demonstrate personally that they have done so[50]. Guidelines from NICE emanate from what may be seen as the *crème de la crème* of authoritative bodies. In addition, NICE guidelines have the underlying rationale of increasing confidence and reducing 'postcode' variations in clinical practice. It is difficult to see how a medical professional could justify ignorance of these guidelines in his or her specialty. Guidelines from NICE are likely to emerge as 'a reasonable body of opinion' for the purpose of litigation, and medical practitioners who deviate from them should be ready to explain why they have done so.

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